

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

**WHAT IS CLAIMED IS:**

1. A method for diagnosing an inflammatory condition, said method comprising:
  - a) measuring the level of pregnancy-associated plasma protein-A (PAPP-A) in a biological sample from a non-pregnant patient;
  - b) comparing said level with that of control subjects; and
  - c) diagnosing said inflammatory condition based on the level of PAPP-A relative to that of control subjects.
2. The method of claim 1, wherein said patient is diagnosed as having said inflammatory condition if the level of PAPP-A is increased relative to that of control subjects.
3. The method of claim 1, wherein said inflammatory condition is acute coronary syndrome.
4. The method of claim 3, wherein said acute coronary syndrome is unstable angina, sudden cardiac death, or acute myocardial infarction.
5. The method of claim 1, wherein said inflammatory condition is rheumatoid arthritis.
6. The method of claim 1, wherein said inflammatory condition is Crohn's disease or inflammatory bowel disease.
7. The method of claim 1, wherein said level of PAPP-A is measured using an immunoassay.
8. The method of claim 7, wherein said immunoassay is an ELISA.
9. The method of claim 8, wherein PAPP-A is captured with anti-PAPP-A polyclonal antibodies.

10. The method of claim 8, wherein PAPP-A is captured with an anti-PAPP-A monoclonal antibody.
11. The method of claim 1, wherein said biological sample is selected from the group consisting of whole blood, plasma, and serum.
12. The method of claim 1, wherein the method further comprises measuring the level of a polypeptide selected from the group consisting of high sensitivity C-reactive protein, creatine kinase MB, troponin I, troponin T, creatine kinase, creatinine, fibrinogen, interleukin-1, and interleukin-6, and wherein said diagnosing step is based on the level of said polypeptide and said level of PAPP-A relative to that of control subjects.
13. An article of manufacture for diagnosing an inflammatory condition in a non-pregnant patient, said article of manufacture comprising an anti-PAPP-A antibody and packaging material, wherein said anti-PAPP-A antibody can be used for measuring PAPP-A levels in a biological sample from said patient, and wherein said packaging material comprises a label or package insert indicating that said anti-PAPP-A antibody can be used for diagnosing said inflammatory condition.
14. The article of manufacture of claim 13, wherein said biological sample is selected from the group consisting of whole blood, plasma, and serum.
15. An article of manufacture for diagnosing an inflammatory condition in a non-pregnant patient, said article of manufacture comprising reagents for measuring levels of a plurality of polypeptides in a biological sample from said patient, wherein said plurality of polypeptides comprises PAPP-A and one or more of the polypeptides selected from the group consisting of high sensitivity C-reactive protein, creatine kinase MB, troponin I, troponin T, creatine kinase, creatinine, fibrinogen, interleukin-1, and interleukin-6.

16. The article of manufacture of claim 15, wherein said biological sample is selected from the group consisting of whole blood, plasma, and serum.
17. A method for diagnosing an inflammatory condition, said method comprising:
  - a) administering to a patient an amount of an antibody having specific binding affinity for PAPP-A effective to detectably bind to PAPP-A, wherein said antibody is labeled;
  - b) detecting the level of said antibody bound to PAPP-A in said patient; and
  - c) diagnosing said inflammatory condition based on the level of said antibody bound to PAPP-A.
18. The method of claim 17, wherein said detecting step comprises diagnostic imaging.
19. The method of claim 18, wherein said diagnostic imaging comprises positron emission tomography, gamma-scintigraphy, single photon emission computerized tomography, magnetic resonance imaging, intravascular ultrasound, or functional magnetic resonance imaging.
20. The method of claim 17, wherein said label is a radioisotope.
21. The method of claim 20, wherein said radioisotope is selected from the group consisting of  $^{123}\text{I}$ ,  $^{18}\text{F}$ ,  $^{111}\text{In}$ ,  $^{67}\text{Ga}$ , and  $^{99\text{m}}\text{Tc}$ .
22. The method of claim 17, wherein said antibody is administered intravenously.